Collection of Pharmaceuticals and Sharps: Responsibilities of Producers (Regulation 298/12)

What's new?
In October 2012, a new regulation came into force requiring producers of pharmaceuticals and sharps to provide for the collection and safe environmental management of their leftover products from consumers by January 1, 2013. Producers must also provide Ontarians with access to free and convenient collection locations, such as pharmacies, to return their leftover pharmaceuticals and sharps.

What materials are producers required to manage?
The regulation applies to leftover or expired pharmaceuticals and sharps (for both humans and pets) that consumers have in their homes and drop off at collection locations, including:

- prescription and over the counter drugs
- natural health products (e.g., vitamins)
- sharps (e.g., needles, EpiPens)
- containers used to transport the above materials to collection locations

The regulation **does not** cover the materials generated in the industrial, commercial or institutional sector, such as from doctors and dentists offices, veterinary offices or hospitals.

Who is obligated?
Individual producers of pharmaceuticals and sharps (e.g., manufacturers, brand owners, or importers) are subject to the regulation. Producers can choose to join other producers to collectively meet the requirements of the regulation.

What are a producer's obligations?
As of January 1, 2013, producers are required to:

- Have a minimum number of collection locations equal to 80 per cent of the number of retail locations where their products are sold ***or*** 80 per cent of the number of pharmacies in Ontario (whichever is less).
- At least one collection location in each municipality in Ontario where the producer's products are sold.
- Undertake promotion and education activities to ensure that consumers are aware of collection locations and know how to safely handle materials before bringing them to a collection location.
- Report publicly through their website on an annual basis on information such as:
  - number and location of each collection location;
  - total quantity of waste collected;
  - how the collected waste was handled, recycled or disposed;

    - nature and effectiveness of their promotion and education activities; and
    - an opinion from a licensed public accountant confirming the accuracy of the information in the report to provide independent assurance that producers have met their requirements.
- An interim report covering the first six months after the regulation takes effect must be made publicly available through the producer's website by June 30, 2013.
- If the reports are written on behalf of a group of producers, the report must also include a list of all participating producers.

The minimum number of collection locations increases to 90 per cent equivalency on January 1, 2014.

What are the consequences of non-compliance?
To achieve compliance and enforcement objectives, the ministry is authorized to use a variety of tools, including education and outreach, warnings, orders and prosecutions. Individuals convicted of an offence under the Environmental Protection Act for not complying with the regulation may be fined up to $100,000 per day while corporations may be fined up to $500,000 per day.

Where can a business get more information?

Visit: **ontario.ca/environment**

Call: **1-800-461-6290 or 416-325-4100**

If any differences exist between this document and the legislation and regulation then the legislation and regulation prevail.

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